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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,127	08/26/2005	Piotr Graczyk	102286.152US1	4051

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WILMER CUTLER PICKERING HALE AND DORR LLP  
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EXAMINER

BALLS, ROBERT J

ART UNIT PAPER NUMBER

1625

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/509,127	<b>Applicant(s)</b> GRACZYK ET AL.	
	<b>Examiner</b> R. James Balls	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13, 16-23, 31, 32, 41-43 and 45-52 is/are pending in the application.
- 4a) Of the above claim(s) 16-23, 31, 32, 41-43, 45-46 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 47-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/10/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-13, 16-23, 31-32, 41-43 and 45-52 are pending.
2. This application is a 371 of PCT/GB03/01115 filed on March 17, 2003, which claims benefit of foreign Application No(s): UNITED KINGDOM 0207488.8 and UNITED KINGDOM 0300400.9 filed on March 28, 2002 and January 8, 2003, respectively.

### ***Election/Restrictions***

3. Applicants traversed the June 6, 2006 requirement for restriction alleging that Inomata et al. (US Patent No. 6,642,375) does not anticipate at least one Markush alternative provided by the instant claims. In support of this position, applicants point to a compound the examiner never suggested was anticipatory (compound 10a in columns 35 and 36 wherein pyrrolopyridine core is substituted with three methyl groups). The examiner, in addition to citing the anticipatory patent number (US 6,642,375), provided a structural depiction and registry number of the anticipatory compound in CAS Document No. 135:43132, a copy of which was included with the requirement for restriction. Within US Patent No. 6,642,375, the anticipatory compound is located in Column 33, under the heading "Synthesis of Compound 9" where it explains that 5-benzofuranyl-7-azaindolenine was used in the synthesis of Compound 9. Therefore, the requirement for restriction is proper and hereby made FINAL.
4. Claims 1-13 and 47-51 wherein R is aryl are currently under examination.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 and 47-51 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to "biohydrolyzable derivatives" of formula I. A definition for this term is not provided in the specification and it's meaning is not clear. This term is indefinite because it does not appraise the public of the metes and bounds of patent protection sought.
6. The claims are drawn to "affinity reagents" of formula I. A definition for this term is not provided in the specification and it's meaning is not clear. This term is indefinite because it does not appraise the public of the metes and bounds of patent protection sought.
7. The claims are drawn to biohydrolyzable derivatives selected from esters, amides, carbamates, carbonates, ureides, and affinity reagents of formula I. See the last few lines of Claim 1. It is not clear what "esters, amides, carbamates, carbonates, ureides and affinity reagents" the claim is referring to. The Markush definitions in the claims already provides for some of these groups such as amides (when R is substituted with  $-NR^2R^2$ ). If this language is referring to compounds other than those defined by formula I but derived by further derivitization, description and support in accordance with 35 USC §112, first paragraph is necessary (see the following 35 USC §112, first paragraph rejectin). For example, if this language refers to an acylated

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moiety for free -COOH, then structures and site of attachment should be disclosed. For purposes of examination, the language will be given its broadest reasonable interpretation and therefore considered to include "esters, amides, carbamates, carbonates, ureides and affinity reagents" of the acylated moieties as well those not explicitly defined by the Markush definitions, for which the following 35 USC §112, first paragraph rejection applies.

***Claim Rejections - 35 USC § 112, Written Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-13 and 47-51 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 1 and dependent claims thereon are drawn to "biohydrolyzable derivatives" selected from "esters, amides, carbamates, carbonates, ureides, solvates, hydrates, affinity reagents and prodrugs thereof."

Terms such as esters, amides, carbamates, carbonates and ureides describe the functional group that links formula I but does not describe where on formula I the linkage exists or to what formula I is being linked to. No guidance is provided in the

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specification in terms of express definitions or exemplified compounds. Therefore, these functional groups can link nearly **any** organic compound, resulting in an infinite number of compounds. Such broad claim language is not supported by the specification. An adequate description requires at least a point of attachment and a positively set forth definition of a finite number of substituents which can link to formula I via these functional groups.

Solvates and hydrates are not compounds of formula I and therefore must have their own description and utility. Solvates are crystalline solid adducts containing solvent molecules within the crystal structure, in either stoichiometric or nonstoichiometric proportions, giving rise to unique differences in the physical and pharmaceutical properties of a compound. If the incorporated solvent is water, a solvate is termed a hydrate. Compared to the pure crystalline forms of a compound, solvates and hydrates usually have significant differences in their physical properties, such as density, hardness, tabletability, refractive index, melting point, enthalpy of fusion, vapor pressure, solubility, dissolution rate, other thermodynamic and kinetic properties. See Vippagunta et al., *Crystalline Solids*, ADVANCED DRUG DELIVERY REVIEWS, 48(1): 3-26 (2001), page 4, third paragraph. The specification contains no structural examples of solvates or hydrates and the specification does not describe a process for making them. Furthermore, no description of the unique physical properties of the claimed solvates and hydrates exist such as the density, hardness melting point, etc.

A "prodrug," is an inactive species that represents an unavailable drug until converted inside the body to its active form. See Bundgaard, DESIGN OF PRODRUGS (Elsevier Science Publishers 1985), page 1. The specification contains no structural examples of prodrugs or guidance as to why and how an appropriate prodrug is made, administered and used to treat disease. Also, a prodrug is a result of rational design usually to overcome physiological obstacles such as solubility problems or toxicity. In the instant case, no description explaining what obstacles the claimed prodrugs are intended to overcome such as solubility problems, toxicity problems, sustained drug release, etc. Therefore, the claimed prodrug is not described in terms of its structure or function.

An affinity group is a chemical modification made to a compound to change the compounds affinity usually by altering its ionic properties, hydrophobic or hydrophilic characteristics, or affinity toward a receptor. See Smulik and Diver, *Synthesis of Cyclosporin A-Derived Affinity Reagents by Olefin Metathesis*, ORGANIC LETTERS, 4(12):2051-2054 (2002). The specification contains no structural examples of affinity reagents or guidance as to why and how an appropriate affinity reagent is made, administered and used to treat disease. Also, it is not clear what obstacles the claimed affinity reagents are intended to overcome. Absent any description, the trm offers no structural limitations and no explanation of what the material is.

Finally, requiring an adequate written description "guards against the inventor's overreaching by later claiming that which he did not invent, by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed

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within his original creation." *Vas-Cath v. Mahurkar*, 935 F.2d at 1561 (Fed.Cir. 1991).

The claims are drawn to biohydrolyzable derivatives" selected from "esters, amides, carbamates, carbonates, ureides, solvates, hydrates, affinity reagents and prodrugs thereof" without positively setting forth the structure of each option. Therefore this broad language reaches through to future compounds not described in the specification or positively set forth in the claims. It encompasses compound not envisioned by applicants and even compounds not yet discovered.

***Claim Rejections - 35 USC § 112, Scope of Enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-13 and 47-51 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for salts of formula I, does not reasonably provide enablement for biohydrolyzable derivatives selected from esters, amides, carbamates, carbonates, ureides, solvates, hydrates, affinity reagents and prodrugs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Knowing how to make and use esters, amides, carbamates, carbonates, ureides, solvates, hydrates, affinity reagents and prodrugs of formula I, requires undue experimentation because their structure and chemical properties are not known, means



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for making them is not taught and one skilled in the art would not know how to use them to treat disease.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916), where the Supreme Court looked to whether the experimentation needed to practice an invention was undue or unreasonable. *Id.* An invention must be described so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Courts rely on the following factors set out in *In re Wands* to determine whether undue experimentation is required to practice a claimed invention:

- (a) The breadth of the claims;
- (b) The nature of the invention and predictability in the art;
- (c) The state of the prior art;
- (d) The level of one of ordinary skill;
- (e) The existence of working examples; and
- (f) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The analysis is applied to the instant case.

(a) The claims are broad. The claims are drawn to esters, amides, carbamates, carbonates, ureides, solvates, hydrates, affinity reagents and prodrugs of formula 1. This scope encompasses an infinite number of chemical compounds for which no chemical structure has been disclosed.

(b) The invention is physiological in nature as it is directed toward pharmaceuticals and treating diseases with those pharmaceuticals, an art which is highly unpredictable. "[T]he scope of enablement varies inversely with the degree of

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unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). In the highly unpredictable pharmaceutical art, the required disclosure is greater than for the disclosure of an invention involving predictable factors such as mechanical or electrical elements. *In re Vaeck*, 20 USPQ 2d 1438 (CAFC 1991).

(c) The state the art is such that a chemist is unable to make a compound for which she does not know the molecular formula. Regarding, esters, amides, carbamates, carbonates, and ureides, no examples are provided in the specification and no definition showing where they connect to the instant compounds and what moieties they attach to the instant compounds exists. Because no description is provided showing the structure of these compounds, the skilled artisan does not know how to make them.

Regarding solvates and hydrates, the state of the art teaches that one cannot predict whether solvates will form or what their composition will be. In the language of the physical chemist, a solvate of organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). West, Anthony R., "Solid State Chemistry and its Applications, Wiley, New York, 1988, pages 358 & 365. The solvent molecule is a species introduced into the crystal and no part of the organic host molecule is left out or replaced. In the first paragraph on page 365, West (Solid State Chemistry) says, "it is not usually possible to predict whether solid solutions will form, or if they do form what is their compositional

extent". Thus, in the absence of experimentation one cannot predict if a particular solvent will solvate any particular crystal. One cannot predict the stoichiometry of the formed solvate, i.e. if one, two, or a half a molecule of solvent added per molecule of host. In the same paragraph on page 365 West (Solid State Chemistry) explains that it is possible to make meta-stable non-equilibrium solvates, further clouding what Applicants mean by the word solvate. Compared with polymorphs, there is an additional degree of freedom to solvates, which means a different solvent or even the moisture of the air that might change the stable region of the solvate.

Prodrugs (and affinity groups) are the result of a rational design to overcome certain physiological obstacles facing a potential drug such as absorption, solubility, receptor binding , or used to maintain a sustained drug release in the body. See Bundgaard, Design of Prodrugs (Elsevier 1985), page 1. The specification contains no structural examples of prodrugs or affinity groups nor does the specification provide guidance as to why and how an appropriate prodrug or affinity group is made, administered and used to treat disease. Also, no evidence showing that a compound is inactive in its prodrug form but active after being metabolized.

(d) The level of skill required to practice the invention is high due to its pharmaceutical nature.

(e) The specification contains no working examples of esters, amides, carbamates, carbonates, ureides, solvates, hydrates, affinity reagents and prodrugs thereof.

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(f) The quantity of experimentation necessary to make or use the disclosed invention is high, based on the unpredictability of the art, the limited guidance in the specification, and the lack of direction and working examples. For example, in terms of prodrugs and affinity groups, no explanation exists as to why a prodrug or affinity group is necessary, i.e. it is not known what physiological obstacles need to be overcome with a prodrug or affinity group. The skilled artisan is required to select a particular prodrug or affinity group, determine how to synthesize the group and the experimentally determine whether the new compound has the desirable utility.

Although a person of ordinary skill in the art is enabled to make/use salts of the instant compounds, he/she would be subjected to undue experimentation in order to make and use esters, amides, carbamates, carbonates, ureides, solvates, hydrates, affinity reagents and prodrugs of formula I.

***Claim Rejections - 35 USC § 112, Written Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 12-13 and 51 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The invention must be described,

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"with such clarity that the reader is assured that the inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection."

*University of Rochester v. G.D. Searle & Co., Inc.*, 249 F. Supp. 2d 216 (W.D.N.Y. 2003) affirmed 358 F.3d 916 (Fed. Cir. 2004). An adequate written description thus "guards against the inventor's overreaching by later claiming that which he did not invent, by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." *Vas-Cath v. Mahurkar*, 935 F.2d at 1561 (Fed.Cir. 1991).

Claims 12-13 and 51 are drawn to pharmaceutical formulations comprising a compound of the instant claims and one or more other active agents including an anti-inflammatory agent (claim 13) or a p-38 inhibitor anti-inflammatory agent (claim 51). A finite list of additional active agents is not provided nor any particular species exemplified. The claims, therefore, encompasses all therapeutic agents (claim 12), all anti-inflammatory agents (claim 13) or all p-38 inhibitor anti-inflammatory agents (claim 51) and reaches through to future compounds not yet known or discovered. This broad scope would give applicants patent protection extending beyond that which is described in the specification, known in the art, or possessed by applicants in violation of 35 U.S.C. §112. For a detailed explanation and commentary on reach-through claims, see LeCointe, *Reach-Through Claims*, INTERNATIONAL PHARMACEUTICAL (2002) (also available at:

<http://www.bakerbotts.com/infocenter/publications/detail.aspx?id=bffe4a7d-5beb-4cf8-a189-15a5f190f0eb>) and Silva, *Reach Through Claims: Bust or Boon?*, INTELLECTUAL

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PROPERTY UPDATE (available at:

<[http://www.dorsey.com/publications/legal\\_detail.aspx?FlashNavID=pubs\\_legal&pubid=170565003](http://www.dorsey.com/publications/legal_detail.aspx?FlashNavID=pubs_legal&pubid=170565003)>).

***Claim Rejections - 35 USC § 112, Enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-13 and 51 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. Claims 12-13 and 51 are drawn to pharmaceutical formulations comprising a compound of the instant claims and one or more other active agents including an anti-inflammatory agent (claim 13) or a p-38 inhibitor anti-inflammatory agent (claim 51). New active agents are continually being discovered. The claim includes active agents known at the time of filing as well as active agents discovered thereafter (including those not yet discovered). No specific compounds are listed, only broad generic classes of therapeutic agents such as anti-inflammatory agents (Claim 51), which can function by a variety of different physiological mechanisms. The specification does not describe what result is desired by combining a compound of the instant claims with another active agent. Furthermore, no physiological characteristics coupled with a known correlation between structure and functions are described.

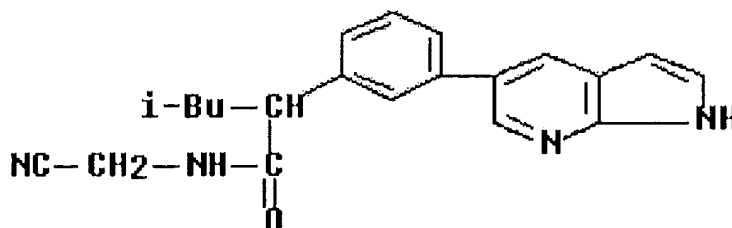
***Claim Rejections - 35 USC § 102(a)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Oballa et al. (WO2001049288). R is phenyl substituted by C<sub>1-12</sub> alkyl, which is substituted by – CONR<sup>2</sup> R<sup>2</sup>, wherein R<sup>2</sup> is Hydrogen and the other R<sup>2</sup> is C<sub>1-12</sub> alkyl substituted with –CN. See page 73, line 4. Also shown CAS Document No. 135:107148, attached hereto.



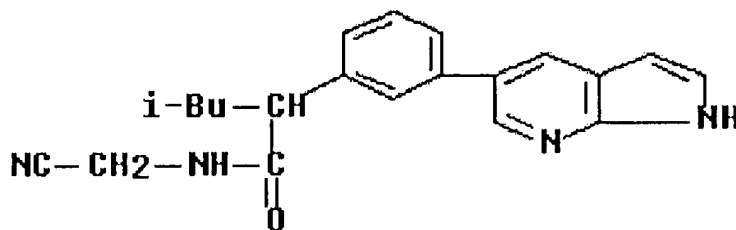
***Claim Rejections - 35 USC § 102(e)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

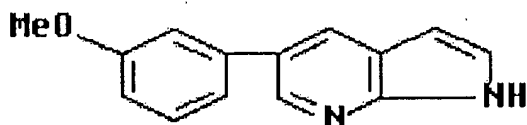
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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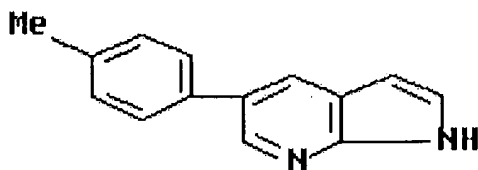
11. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Oballa et al. (WO2001049288). R is phenyl substituted by C<sub>1-12</sub> alkyl, which is substituted by –CONR<sup>2</sup> R<sup>2</sup>, wherein R<sup>2</sup> is Hydrogen and the other R<sup>2</sup> is C<sub>1-12</sub> alkyl substituted with –CN.



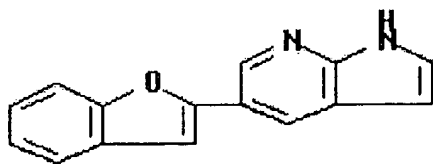
12. Claims 1-4, 6-7 and 47, 49-50 are rejected under 35 U.S.C. §102(e) as being anticipated by Inomata et al. CAS Document No. 135:43132, corresponding to US 6,642,375. See the compounds named in US 6,642,375 in Column 33, line 7, Column 33, line 65 and Column 41, lines 65-66.



STN No. 344454-28-0



STN No. 344454-45-1



STN No. 344454-31-5



***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-13 and 47-51 are rejected under 35 U.S.C. §103(a) as being unpatentable over Inomata et al. CAS Document No. 135:43132 in view of Inomata et al., US Patent No. 6,642,375 (the compounds shown in columns 21-23).

**Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

Anticipatory compounds are disclosed in Inomata et al. See Column 33, line 7, Column 33, line 65 and Column 41, lines 65-66. Final products made from structurally analogous starting materials are shown in columns 21-23.

**Ascertainment of the Difference Between the Prior Art and the Claims (MPEP §2141.02)**

The difference between the instant claims and the prior art is that the prior art compounds listed in Columns 21-23 show the final products without delineation of the corresponding intermediates or starting materials.

**Motivation and Prima Facie Obviousness-Rationale (MPEP §§2142-2143)**

One of ordinary skill in the art would be motivated to arrive at the instant compounds based on final products disclosed in Inomata et al. Inomata et al. discloses acylated final products but non-acylated intermediates. Thus, the skilled artisan would be in possession of the non-acylated intermediates necessary for the manufacture of the corresponding final products.

***Conclusion***

14. No claims are allowed.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. James Balls whose telephone number is (571) 272-7997. The examiner can normally be reached on Mon - Fri 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom McKenzie can be reached on (571) 272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R. James Balls  
November 2, 2006



Celia Chang  
Primary Examiner  
Art Unit 1625